2. 510(K) SUMMARY

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Biosense Webster, Inc. 3333 Diamond Canyon Road Diamond Bar, CA 91765
OFFICIAL CORRESPONDENT	Wayne R. Hohman Project Manager Regulatory Affairs Telephone: 909-839-8597 Fax: 909-839-8804 Email: whohman@its.jnj.com
TRADE NAME	PENTARAY® NAV High-Density Mapping Catheter
COMMON NAME	Deflectable Tip Electrophysiology Catheter—Diagnostic
CLASSIFICATION NAME	Electrode recording catheter or electrode recording probe
DEVICE CLASSIFICATION	Class II, 21 CFR §870.1220 Product Code: MTD
PRODUCT CODES	D-1282-01-S, D-1282-02-S, D-1282-03-S D-1282-04-S, D-1282-05-S, D-1282-06-S
PREDICATE DEVICE	Biosense Webster Flower High-Density Mapping Catheter (510(k) K050217), now named the PENTARAY® High-Density Mapping Catheter
REFERENCE DEVICE	Biosense Webster LASSO® 2515 NAV Variable Catheter (510(k) K081258)

SUBSTANTIALLY EQUIVALENT TO:

PENTARAY® NAV High-Density Mapping Catheter is substantially equivalent to Biosense Webster's Flower High-Density Mapping Catheter (510(k) K050217), now named the PENTARAY® High-Density Mapping Catheter, and a Reference Device, the Biosense Webster LASSO® 2515 NAV Variable Catheter (510(k) K081258). Like the predicate device, the PENTARAY® NAV High-Density Mapping Catheter features a five-spine array of 20 electrodes at the distal tip of a 7 Fr diameter catheter, has the same patient contact materials, and has the same device geometry. The original intended use of the predicate device for diagnosis of heart arrhythmias remains the same in the proposed

device, however the proposed device will now have the added ability to provide location information when used with the CARTO® 3 EP Navigation System, Version 3.0. This latter capability is substantially equivalent to the Reference Device, the LASSO® 2515 NAV Variable Catheter. The LASSO® 2515 NAV Variable Catheter went through this same transition with FDA when FDA cleared the update of the non-navigational version to the navigational version.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The PENTARAY® NAV High-Density Mapping Catheter is a 7 Fr, multi-electrode, electrophysiological diagnostic mapping catheter that consists of an array of five flexible spines that support a total of 20 Platinum/Iridium ring mapping electrodes (four electrodes per spine). The five spines converge at a multi-lumen soft tip section of the catheter that is deflectable (a minimum of 160°) and maneuverable by the user. These features permit positioning the flexible electrode-bearing spines against the heart wall to monitor electrical activity. The new feature is an electromagnetic location sensor located within the soft tip of the shaft. Two new ring electrodes are positioned on the exterior of the shaft in this same area. The electrical wires from the 22 electrodes, the sensor, the puller wires that effect deflection, and a plastic tube for heparinized saline run through the length of the catheter shaft to the handle. The handle is used to advance or retract the catheter, torque the catheter, and/or deflect the catheter to optimize positioning of the multi-spined tip. The catheter is connected via appropriate cables to the CARTO® 3 EP Navigation System and/or appropriate recording equipment.

INDICATIONS FOR USE:

The Biosense Webster PENTARAY® NAV High-Density Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart. The PENTARAY® NAV High-Density Mapping Catheter provides location information when used with compatible CARTO® 3 V3.0 EP Navigation Systems. (This catheter is not compatible with CARTO®3 EP Navigation Systems prior to Version 3.0.)

TECHNICAL CHARACTERISTICS:

The PENTARAY® NAV High-Density Mapping Catheter is a typical electrophysiological catheter that is unique only in its geometrical arrangement of 20 ring electrodes on five individual spines at its distal tip. Otherwise, there are no special technical aspects of the ability of this catheter to detect electrical signals from heart endocardium and transmit this information to the CARTO® 3 EP Navigation System and/or recording equipment for display, analysis, and interpretation in detection of various heart arrhythmias.

PERFORMANCE DATA:

The PENTARAY® NAV High-Density Mapping Catheter underwent extensive Bench Testing that included simulated use conditions. After thorough investigations and mitigations where appropriate, the proposed catheter passed all intended criteria in accordance with appropriate test criteria and standards.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

A technological comparison and performance testing demonstrate that the PENTARAY® NAV High-Density Mapping Catheter is substantially equivalent to the predicate and reference devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 2 4 2012

Biosense Webster, Inc.
c/o Mr. Wayne Hohman
Project Manager Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K120425
Trade/Device Name: Pentaray Nav High-Density Mapping Catheter
Regulation Number: 21 CFR §870.1220
Regulation Name: Catheter, Electrode Recording
Regulatory Class: Class II (two)
Product Code: MTD
Dated: May 9, 2012
Received: May 10, 2012

Dear Mr. Hohman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120425 1/1

SECTION 1. INDICATIONS FOR USE STATEMENT

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: PENTARAY® NAV High-Density Mapping Catheter

Indications for Use:

The Biosense Webster PENTARAY® NAV High-Density Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart. The PENTARAY® NAV High-Density Mapping Catheter provides location information when used with compatible CARTO® 3 EP Navigation Systems. (This catheter is not compatible with CARTO® 3 EP Navigation Systems prior to Version 3.0.)

Contraindications

- The Biosense Webster PENTARAY® NAV High-Density Mapping Catheter has not been shown to be safe and effective for radio frequency (RF) ablation.
- Use of this catheter may not be appropriate for use in patients with prosthetic valves. A relative contraindication for cardiac catheter procedures is active systemic infection.
- The transseptal approach is contraindicated in patients with intracardiac thrombus or myxoma, or interatrial baffle or patch.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120425